34.   (NEW) The system of claim 16 wherein the record client further comprises a data reader that reads the verification data from the package.

35.   (NEW) The system of claim 16 wherein the record client further comprises an image data capture device that generates image data, and the verification data includes the image data.

REMARKS

Claims 1 through 22 are pending in the present application. New claims 23 through 35 are herewith presented for examination. In an office action mailed September 12, 2002 (Paper No. 8), claims 16 through 19 were rejected under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim which applicant regards as the invention. Claims 1 through 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,924,074 granted to Evans (hereinafter "*Evans*") in view of U.S. Patent 5,899,998 granted to McGauley et al. (hereinafter "*McGauley*"). Claims 16, 17 and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Evans* in light of U.S. Patent 6,305,377 to Portwood et al. (hereinafter "*Portwood*"). Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over *Evans* in light of *Portwood* and further in view of *McGauley*. Claims 20 through 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Portwood* in view of *Evans*. These rejections are respectfully traversed.

Rejections under 35 U.S.C. 112

Claims 16 through 19 stand rejected under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim which applicant regards as the invention. In particular, it is stated that it is "unclear as to which element [of claim 16] performs the 'distributing' functions recited in the preamble." These rejections are respectfully traversed.

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The Applicants believe that the term "distributing" is being read too narrowly. For example, claim 16 states "a record server receiving **package data**; a record client coupled to the record server, the record client receiving the **package data** from the record server and **verification data**; and wherein the record server receives the **verification data** from the record client and correlates the **verification data** to the **package data**." One exemplary embodiment in which such a system could be used would include a first location in which the **package data** is entered when the package, such as a package of prescription medicines, is created, such as by a licensed pharmacist, and in a second location where the package is distributed to a patient without a licensed pharmacist present, where the **verification data** is provided to create a record that the correct package has been provided to the correct patient. Thus, the system allows medical supplies to be distributed where they otherwise would not be able to be distributed, i.e., where no licensed pharmacist is present. Applicants believe that claims 16 through 19 are clear when read in light of the specification, which describes this and other exemplary embodiments, and request that the rejection of these claims under 35 U.S.C. 112 be withdrawn.

Rejections under 35 U.S.C. 103

Claims 1 through 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Evans* in view of *McGauley*. In particular, it is asserted that *Evans* teaches "a system for transferring electronic medical files," and that *McGauley* teaches "a method and system for maintaining and updating computerized medical records that use encryption." This rejection is respectfully traversed.

Evans in view of *McGauley* fails to provide a prima facie basis for the rejection of claims 1 through 15, because they fail to disclose each element of the claimed invention. As noted by the Examiner, *Evans* fails to disclose that the medical record data is encapsulated to prevent modification of the medical record data. *McGauley* also fails to disclose encapsulation. For example, *McGauley* states at col. 6, lines 44 through 48 that communications between modems

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"are encrypted to help protect the security of the system and to preserve the confidentiality of individual patient's medical information." However, **encryption is not synonymous to encapsulation**. Claim 1 includes "a record server having a medical record data file, the medical record data file having medical record data; a record client coupled to the record server, the record client receiving the medical record data file; and wherein the medical record data is encapsulated to prevent modification of the medical record data." As stated in paragraph 8 of the specification in regards to one exemplary embodiment of the invention, the "medical record data is encapsulated to prevent modification of the medical record data, thus providing for integrity and continuity of the patient's medical record." Thus, unlike *McGauley* in which the data can be modified at each POS station 110, the invention of claim 1 can prevent modification of medical record data. The medical record data can also be encrypted as it is transmitted, but claim 1 does not require encryption.

Claim 2 further includes "the record server further comprises a sync system verifying that the record client has received a sync file before transferring the medical record data file." It is alleged that this "feature is met by the electronic medical record system including web servers (406, Fig. 24) that allow patient data to be transfer between external source as well as updating the patient record obviously suggesting that the comparing and checking of medical data takes place to verify that an up-to-date medical record is available." *Citing Evans*, col. 3, lines 37-43 and col. 5, lines 36-40. If *Evans* merely "obviously suggests" this element of the invention, then it fails to disclose it and thus fails to provide a prima facie basis for the rejection of claim 2. Nevertheless, *Evans* fails to even suggest the sync system of claim 2. Nothing in *Evans* would prevent the transmission of incorrect patient data, as this could be caused by human error. For example, if the web servers of *Evans* were used to transmit patient data, an operator could transmit the wrong patient data to the external source, which would then update the patient record at the external source without checking to verify that the patient data is related to that patient record. While an "up-to-date medical record" would then be available, it would be an up-to-date medical record that has been corrupted with incorrect patient data. In one exemplary

embodiment, the sync system of claim 2 can be used to verify that the record client has received a sync file before transferring the medical record data file such that operator error can be prevented (in addition to providing other useful functions). Neither *Evans* nor *McGauley* disclose a sync file or a sync system, and neither provides encapsulation.

Claim 3 further includes "the record server further comprises a tracking system updating a tracking record when the medical record data file is transferred." Claim 4 further includes "the record client further comprises tracking system updating a tracking record when the medical record data file is transferred." The cited section of *Evans* at col. 9, lines 27 through 37 and col. 5, lines 29 through 40 does not disclose "a tracking system updating a tracking record when the medical record data file has been accessed," but only tracking "the location and description of patient data within the data archive 208," and updating "the patient record 112 to include the complaint and other information pertinent to the appointment, such as insurance information." Thus, *Evans* discloses no tracking **record**, only the tracking of the location and description of patient data and updating the patient record to include the complaint and other such information. What if no patient data, complaint or other pertinent information is provided? In one exemplary embodiment, claims 3 and 4 would allow verification that a medical record data file was seen at the location of the record server or the record client, even where no such complaint or other pertinent information is provided, such as to establish whether a practitioner at the record server or the record client ever viewed the medical record data file. For example, if a practitioner prescribes medicine that later is determined to be inappropriate, it may be important to determine whether the patient's medical record data file was ever accessed by that practitioner. *Evans* would not provide that functionality in that exemplary embodiment, whereas the invention of either claim 3 or claim 4 would (in addition to other useful functions), depending on the location of the practitioner. Likewise, if a patient record was updated after a practitioner accessed the record, then the state of the record would be material to determining whether the practitioner provided a proper diagnosis. Because the medical record data of claim 3 and claim 4 is encapsulated, it is possible to determine in this exemplary embodiment what the state of the

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record was at a given time, whereas neither *Evans* nor *McGauley*, either alone or in combination, track access, much less at different locations, and neither provides encapsulation.

Claim 5 further includes a "remote data system generating medical record data, wherein the record client encapsulates the medical record data to prevent it from being modified." In one exemplary embodiment, if a practitioner in a remote location supplements the medical record data, such as by providing a diagnosis, the invention of claim 5 allows that data to be encapsulated so as to provide a record of the diagnosis or of any other data provided by the practitioner at that time, thus allowing an accurate record to be kept of the state of the medical record data as it is supplemented over time, in addition to other useful functions. Neither *Evans* nor *McGauley*, either alone or in combination, provide encapsulation, much less at a remote data system.

Claim 6 further includes "a detail encapsulation system receiving comment data and encapsulating the comment data to prevent it from being modified." Thus, in one exemplary embodiment, comment data can thus be received that is independent from the medical record, such as where available data transmission bandwidth prevents transmission of the entire record. The comment data once entered is prevented from being modified by the invention of claim 6, in addition to other useful functions. Neither *Evans* nor *McGauley*, either alone or in combination, provide encapsulation, much less encapsulation of comment data.

Claim 7 includes a "record storage system storing each version of the medical record data file received by the record server." In one exemplary embodiment, it may be necessary to determine whether data in one version of the medical record data file, such as diagnosis data that was encapsulated, is the same in a later version of the medical record data file, such as to address a claim that the diagnosis data has been modified to correct an earlier incorrect diagnosis. The invention of claim 7 would allow such claims to be addressed, as well as providing other useful functions. Neither *Evans* nor *McGauley*, either alone or in combination, would provide such

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functionality, and instead allow records to be modified without storage of versions, much less encapsulated versions that prevent modification or tampering.

Claim 8 includes "an excerpt transfer system, the excerpt transfer system receiving medical record excerpt data and transferring it to a predetermined recipient." In one exemplary embodiment, depending on the size of a medical record data file, transmission of the entire file to a predetermined recipient could be prohibited by data transmission capabilities. In another exemplary embodiment, a predetermined recipient may only require or be authorized to view a portion of the medical record data file. The invention of claim 8 allows excerpts of encapsulated data to be transferred in such situations, in addition to providing other useful functions. Neither *Evans* nor *McGauley*, either alone or in combination, would provide such functionality, and instead require the entire record to be transferred, as well as failing to provide encapsulation.

Claim 9 includes "a notification system transferring notification data to a party regarding the availability of medical record data." The cited portion of *Evans* pertains to "acknowledgement . . . that a patient's record has been reviewed." Clearly, if a practitioner is never even made aware that medical record data is available, they will never be in a position to acknowledge that it has been reviewed. In one exemplary embodiment, a practitioner may desire confirmation of a diagnosis or for other data to be provided by another party. Neither *Evans* nor *McGauley*, either alone or in combination, would allow a party to be notified regarding the availability of medical record data, much less encapsulated medical record data.

Claim 10 includes "encapsulating medical record data to prevent it from being modified; assembling the medical record data into a medical record data file; receiving a request to transfer the medical record data file; and transferring the medical record data file to a remote location." Unlike *McGauley*, in which the data is encrypted only prior to transmission between modems, the medical record data of claim 10 is encapsulated prior to assembling the medical record data into a medical record data file and before receiving a request to transfer the medical record. Thus, it

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is clear from the claim language that **encryption is not synonymous to encapsulation**. While the claimed invention does not prohibit encryption, neither does it require encryption.

Claim 11 includes "transferring a sync file to the remote location." Neither *Evans* nor *McGauley* either alone or in combination disclose a sync file, much less transferring it to a remote location and encapsulation, as previously discussed. Claim 12 includes "storing a tracking record with the medical record data file." Neither *Evans* nor *McGauley*, either alone or in combination, disclose a tracking record, much less storing it with the medical record data file and encapsulation, as previously discussed. Claim 13 includes "generating notification data at the remote location." Neither *Evans* nor *McGauley*, either alone or in combination, disclose generating notification data, much less encapsulation, as previously discussed. Claim 14 includes "updating a tracking record to show that the medical record data file has been accessed at the remote location." Neither *Evans* nor *McGauley*, either alone or in combination, disclose a tracking record, much less encapsulation, as previously discussed. Claim 15 includes "receiving medical record data at the remote location; encapsulating the medical record data to prevent the medical record data from being modified; and updating the medical record data file to include the medical record data." Neither *Evans* nor *McGauley*, either alone or in combination, disclose encapsulating medical record data at a remote location and updating the medical record data file to include the medical record data, as previously discussed.

For these reasons and for other reasons readily apparent, Applicants request that the rejection of claims 1 through 15 under 35 U.S.C. 103(a) as being unpatentable over *Evans* in view of *McGauley* be withdrawn, and that these claims be allowed to issue.

Claims 16, 17 and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Evans* in view of *Portwood*. In particular, it is asserted that *Portwood* discloses a "prescription distribution system including a server computer communicating with other prescriber computer to transfer prescription data *to the server* for validation, certification, and distribution."

(Emphasis added). This rejection is respectfully traversed.

As a preliminary matter, the characterization of *Portwood* as a "prescription distribution system" contrasts with the rejection of claims 16 through 19 under 35 U.S.C. 112. As the Examiner asks in regards to claims 16 through 19, what element of *Portwood* performs the act of "distributing" a prescription? The Applicants believe that one of skill in the art would understand the use of the invention of claims 16 through 19 for distributing medical supplies in the same manner that the Examiner understood *Portwood* to be a "prescription distribution system."

Claim 16 includes "a record server receiving package data; a record client coupled to the record server, the record client receiving the package data from the record server and verification data; and wherein the record server receives the verification data from the record client and correlates the verification data to the package data." Thus, using the invention of claim 16 in one exemplary embodiment, it would be possible for a licensed pharmacist to assemble a package that includes controlled medication, and to verify that the person receiving the package at a remote location is the person to whom the medication was prescribed. *Portwood* fails to provide such exemplary functionality. For example, using *Portwood*, it would be necessary for the licensed pharmacist to be present at the *prescription station* to dispense the controlled medication. *Portwood*, col. 7, lines 5 through 10. *Portwood* would not perform the function of claim 16, because it does not disclose a record server receiving package data; a record client coupled to the record server, the record client receiving the package data from the record server and verification data; and wherein the record server receives the verification data from the record client and correlates the verification data to the package data.

Claim 17 includes "an inventory tracking system receiving the verification data and incrementing order data." Thus, using the invention of claim 17 in one exemplary embodiment, a number of packages of controlled medication could be assembled and remotely stored in a

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controlled location, and order data for replenishing the remote store of packages can be generated when each package is distributed by personnel other than a licensed pharmacist. *Portwood* fails to provide this functionality, as it requires the licensed pharmacist to be present at the prescription station. Verification data is therefore not required and never generated nor received in the system of *Portwood*, and therefore order data could not be incremented upon receipt of verification data in the system of *Portwood*.

Claim 19 includes a "remote data system generating counseling data and transmitting the counseling data to the record server." In one exemplary embodiment, when a patient receives a controlled medicine for the first time, it may be necessary to confirm that the patient received counseling data, but a licensed pharmacist does not need to perform that verification. Typically, the patient signs a form stating that they have received counseling, which must then be filed where it is signed. The invention of claim 19 allows an image of the signed form or other suitable counseling data to be transmitted to a record server, thus avoiding the need to store such counseling data locally. *Portwood* entirely fails to disclose functionality that would allow this process, in addition to requiring a licensed pharmacist to be present at the prescription station, thus eliminating any motivation for the generation of package data or verification data.

For these reasons and for other reasons readily apparent, Applicants request that the rejection of claims 16, 17 and 19 under 35 U.S.C. 103(a) as being unpatentable over *Evans* in view of *Portwood* be withdrawn, and that these claims be allowed to issue.

Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over *Evans* in light of *Portwood* and further in view of *McGauley*, and includes a "record encapsulation system receiving the verification data and encapsulating the verification data in a medical record data file." As previously discussed, *McGauley* discloses encryption, and not encapsulation. Furthermore, as *Portwood* requires a licensed pharmacist to be present when controlled medicine is provided to a patient, it provides no motivation for the generation of package data or

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verification data. For these reasons and for other reasons readily apparent, Applicants request that the rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over *Evans* in view of *Portwood* and *McGauley* be withdrawn, and that this claim be allowed to issue.

Claims 20 through 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Portwood* in view of *Evans*. Claim 20 includes "storing package data corresponding to a sealed package; transmitting the sealed package to a remote site; receiving the package data from the remote site; and authorizing release of the package if the stored package data matches the received package data." Claim 21 includes "counseling a patient if the patient has not received the medical supplies before; and generating counseling data." Claim 22 includes "incrementing order data after the package is released." As previously discussed, *Portwood* requires the licensed pharmacist to be present when the controlled medication is released to the patient, such that a sealed package is never transmitted to a remote site, and stored package data is never matched to received package data using the system of *Portwood*. For these reasons and for other reasons readily apparent, Applicants request that the rejection of claims 20 through 22 under 35 U.S.C. 103(a) as being unpatentable over *Portwood* in view of *Evans* be withdrawn, and that these claims be allowed to issue.
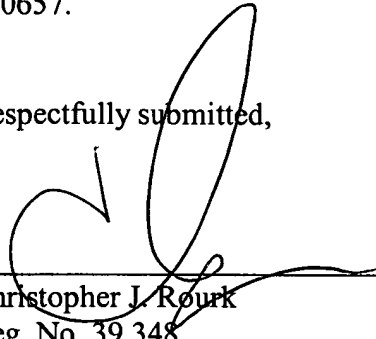
CONCLUSION

In view of the foregoing remarks and for various other reasons readily apparent, Applicants submit that all of the claims now present are allowable, and withdrawal of the rejection and a Notice of Allowance are courteously solicited.

If any impediment to the allowance of the claims remains after consideration of this amendment, and such impediment could be alleviated during a telephone interview, the Examiner is invited to telephone the undersigned at (214) 969-4669 so that such issues may be resolved as expeditiously as possible.

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A fee of $285.00 is believed to be due for four additional independent claims and nine additional dependent claims. If any applicable fee or refund has been overlooked, the Commissioner is hereby authorized to charge any fee or credit any refund to the deposit account of Akin, Gump, Strauss, Hauer & Feld, L.L.P., No. 01-0657.

Respectfully submitted,

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